

SEP 25 2007

Remarks and argument

Claims 1-5, 7, 11-12, 16-35, 37-39, 41-43, 45-46, and 55-63 are pending in this application. Claims 1, 55 and 61 are independent.

Claims 1 and 46 are amended. Claim 1 is amended to incorporate part of the subject matter of claim 13. No new matter is added.

The amendment to claim 46 is not of any substantive matter. In the previous office action, Applicant erroneously used the square bracket style rather than strike through for deletions. The correct form has now been used. For this reason, Applicant respectfully submits that the amendment is purely formal in nature and no reduction in available scope of equivalents under the Doctrine of Equivalents should attach by virtue of this amendment.

Claims 13, 47-54 are canceled without prejudice. Claims 47-54 have been withdrawn subject to a restriction requirement.

New claims 55-63 are added. Support for these claims is found throughout the specification and the claims originally filed. No new matter is added.

Reconsideration is respectfully requested.

I. Rejection under 35 U.S.C. 103(a)

1. Claims 1-5, 7, 11-13, 16-35, 37-39, 41-43 and 45-46 are rejected under 35 U.S.C. 103(a) as being unpatentable over Show Denko KK JP 62096408 in view of Pera U.S. Patent No. 4,775,525. and Elliott et al. U.S. Patent No. 5,011,682.

The claims are drawn to a composition comprising ascorbyl-2-phosphate or a sodium or potassium salt thereof and further comprising calcium ions wherein the composition is mixed with an orally acceptable carrier, and further comprising a calcium chelating agent, a pyrophosphate, tripolyphosphate or

polyphosphate tartar control agent, a water soluble fluid, water soluble solid, humectant, thickener, surfactant, sweetener, flavorant, colorant, abrasive, stabilizer, fluoride containing compound, anticaries agent, antimicrobial agent, essential oil and a desensitizing agent.

Showa Denko KK teach ascorbic acid phosphoric acid ester or it's salt (e.g. Na^+ , K^+ Ca^{++} or Mg^+ salt) in an oral composition to be used for alveolar pyorrhea, cleaning teeth, removing bad breath and washing the teeth. It is in compositions such as toothpaste, chewing gum and troches. Working example I teaches calcium diphosphate dihydrate (source of calcium/abrasive), sodium carboxymethylcellulose and carrageenan (thickeners), glycerin (water soluble liquid), sorbital (water soluble solid), fragrance (flavor), preservative (antimicrobial), sodium saccharin (sweetener), sodium lauryl sulfate (surfactant), and ascorbic acid magnesium phosphate.

Showa Denko does not teach the desensitizing agents of claims 40-44, it does not teach the non water-soluble solid and liquid and it does not teach the pyrophosphate, tripolyphosphate or polyphosphate tartar control agent.

Pera (4,775,525) teaches strontium as a desensitizing agent for the teeth (column 5, lines 27-43).

It would have been made obvious to one of ordinary skill in art at the time it was made to incorporate desensitizing agents and vegetable oils and wax. Such a modification would have been motivated by the reasoned expectation of producing a dentifrice composition which is effective in comprehensively cleaning teeth and desensitizing teeth of individuals that have become sensitized. Strontium is a well known desensitizer, which is known and used in dentifrices as evidenced by the teachings of Pera (4,775,525). Vegetable oil would aid in mixing the dentifrice composition and the wax would effectively coat the teeth and add shine to the teeth.

Elliott et al. teach Soluble inorganic pyrophosphate salts have over the last few years set the commercial standard as tartar control agents (column 1, lines 26-31) and teach tartar control agents such as disodium pyrophosphate, dipotassium pyrophosphate, tetrapotassium pyrophosphate, tetrasodium pyrophosphate to a dentifrice composition (column 5, lines 5-16).

It would have been made obvious to one of ordinary skill in art at the time it was made to incorporate the instantly recited tartar control agents. Such a modification would have been motivated by the reasoned expectation of producing a dentifrice composition, which is effective in comprehensively cleaning teeth and removing tartar. As stated in Elliott, the pyrophosphate tartar control agents have set the commercial standard and are known and used in dentifrices as evidenced by the teachings of Elliott et al.

Applicant claims a pH of the composition from about 5.5 to about 10.0 now in independent claim 1. However, if applicant wishes to rely on provisional application number 60/263884, for a priority date of 1/24/01, the only pH present in the priority document is a teaching of a pH of 8.86 in one specific formulation. There is no recitation of a pH of from about 5.5 to about 10.

See <http://pubs.acs.org/hotartcl/chemtech/95/dec/dec.html> December 1995 wherein it is recited that Sodium fluoride, sodium monofluorophosphate, and stannous fluoride are the most common fluoride sources used in toothpaste. Great care must be taken in the formulation of these agents so that their anticaries activity is not reduced by other dentifrice ingredients, such as the abrasive system. For example, whereas sodium monofluorophosphate is compatible with both silica and dicalcium phosphate dihydrate abrasives, sodium fluoride is most compatible with the silica abrasive at neutral pH values. Thus it would have been obvious to employ a pH of 5.5 to 10 since this range

encompasses neutral pH's and this would be most compatible for formulations with fluoride.

Applicant respectfully traverses the rejection.

Showa Denko KK teach ascorbic acid phosphoric acid ester or it's salt (e.g. Na⁺, K⁺ Ca⁺⁺ or Mg⁺ salt) in an oral composition to be used for alveolar pyorrhea, cleaning teeth, removing bad breath and washing the teeth. It is in compositions such as toothpaste, chewing gum and troches. However, since calcium diphosphate dehydrate is taught as an abrasive, large amounts of the material is used, specifically 45%. There is no teaching of a tartar control agent in the amounts of about 1 to about 4% of the composition in combination with an ascorbyl-2-phosphate compound, or a sodium or potassium salt thereof, at a pH of about 5.5 to about 10. See amended claim 1 of the present invention.

Pera U.S. Patent No. 4,775,525 discloses "providing an ingestible toothpaste which when used on a daily basis, is primarily intended to remove dental plaque and secondarily intended to reduce hypersensitivity, and halitosis." See Col. 3, lines 42-46, emphasis added. "The essential active ingredient of the present invention is a calcium ion chelating agent comprising sodium alginate. The removal of calcium ions weakens plaque so that it may be easily removed by brushing or other mild forms of abrading actions." See Col. 3, lines 51-55. Thus, Pera essentially teaches the use of sodium alginate as a plaque removal agent in an ingestible toothpaste and teach away from the use of normal tartar control agents and abrasives. "In general, while no abrasive is harsh enough to remove enamel, some dentifrices may harm cementum and dentin. These products should be avoided by individuals with periodontal disease and hypersensitive teeth. Identifying the different kinds of offending dentifrices is difficult because the interaction of inert ingredients in each formula (which changes over time) may enhance or retard the effect of the abrasive within the

mixture. In general, powders are more abrasive than pastes, and products that claim to be tooth whiteners often are harsher than others. Specific abrasive ingredients which may harm dentin include calcium carbonate, anhydrous dibasic calcium phosphate and silica." See Col. 1, line 57 to Col. 2, line 3. (Emphasis added).

Elliott et al. U.S. Patent No. 5,011,682 discloses yet another anti-tartar agent having "a random polymeric residue comprising at least one unit of structure II". See Col. 2, lines 22-45. "When in the form of a toothpaste or gel, the oral compositions will normally include an abrasive. Abrasives may be selected from water-insoluble alkali or alkaline earth metal salts of metaphosphate, calcium carbonate, aluminates and silicates. Especially preferred are silicate, dicalcium phosphate and calcium carbonate. Amounts of the abrasive will range from about 5% to about 80% by weight." See Co. 4, line 65 to Col. 5, line 4. (Emphasis added). "Adjunct tartar control agents, especially those containing phosphorous, may be combined with the polymers of the present invention. Inorganic phosphorous adjuncts may include any of the water-soluble pyrophosphates such as disodium pyrophosphate, dipotassium pyrophosphate and mixtures of these with tetrapotassium pyrophosphates or tetrasodium pyrophosphates. Organic phosphorous compounds that may serve as adjuncts include polyphosphonates such as disodium ethane-1-hydroxy-1, 1-diphosphonate (EHDP), methanediphosphonic acid, and 2-phosphonobutane-1,2,4-tricarboxylic acid." See Col. 5, lines 5-25. Thus, while Elliott et al. discloses that "soluble inorganic pyrophosphate salts have over the last few years set the commercial standard as tartar control agents" (column 1, lines 26-31) and that "tartar control agents such as disodium pyrophosphate, dipotassium pyrophosphate, tetrapotassium pyrophosphate, tetrasodium pyrophosphate" may be added to a dentifrice composition" (column 5, lines 5-16), Elliott

essentially teaches away from such tartar control materials, except for use as abrasive agents, in favor of "a random polymeric residue comprising at least one unit of structure II".

Therefore, neither Pera nor Elliott or both supplies the deficiencies of Showa Denko KK, and actually teaches away from the present invention.

The article of <http://pubs.acs.org/hotartcl/chemtech/95/dec/dec.html> December 1995 cited by the Examiner may teach what the Examiner notes, i.e., "wherein it is recited that Sodium fluoride, sodium monofluorophosphate, and stannous fluoride are the most common fluoride sources used in toothpaste. Great care must be taken in the formulation of these agents so that their anticaries activity is not reduced by other dentifrice ingredients, such as the abrasive system. For example, whereas sodium monofluorophosphate is compatible with both silica and dicalcium phosphate dihydrate abrasives, sodium fluoride is most compatible with the silica abrasive at neutral pH values". However, this reference also teaches away from the instant invention because knowing that a neutral pH is desired does not supply the deficiencies of Show Denko KK JP 62096408 in view of Pera U.S. Patent No. 4,775,525 and Elliott et al. U.S. Patent No. 5,011,682.

Additionally, Applicant respectfully submits that the Examiner's reasoning is hind sight reconstruction, using Applicant's invention as a template. Absent Applicant's invention, there is no teaching of how to pick and choose bits and pieces from the prior art. Even if such bits and pieces are chosen, there will still be no invention without adding insight from Applicant's teaching.

Applicant respectfully requests that the rejection of claims 1-5, 7, 11-13, 16-35, 37-39, 41-43 and 45-46 under 35 U.S.C. 103(a) as being unpatentable over Show Denko KK JP 62096408 in view of Pera U.S. Patent No. 4,775,525. and

SEP 25 2007

Elliott et al. U.S. Patent No. 5,011,682 be withdrawn. Reconsideration is respectfully requested.

As for the Examiner note that if applicant wishes to rely on provisional application number 60/263884, for a priority date of 1/24/01, the only pH present in the priority document is a teaching of a pH of 8.86 in one specific formulation and that there is no recitation of a pH of from about 5.5 to about 10, Applicant respectfully submits that Applicant's claim of a pH of the composition from about 5.5 to about 10.0 now in independent claim 1 is fully supported by the provisional application. In the provisional application, the compositions listed on page 3, cover a large range of compositions whose pH is in the range of about 5.5 to about 10. For example, sodium ascorbyl phosphate has a pH of 9-10 at a 3% solution. See <http://www.sciencelab.com/page/S/PVAR/10426/SLS3580>. A 0.4 M solution (1.68%) of sodium fluoride (molecular weight of 42) has a pH 3 to 4. See <http://www.pubmedcentral.nih.gov/articlerender.fcgi?artid=243760>. Based on these known values, it can be seen that the pH range is about 5.5 to about 10. Reconsideration is respectfully requested.

II. New Claim Rejections -35 USC § 112

Claims 13, 35, 39, 43 and 46 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Applicant respectfully traverses the rejection.

Claims 13, 35, 39 and 43 are presented in what Applicant believes to be a correct Markush format, comprising one range of values or another range of values. Reconsideration is respectfully requested.

SEP 25 2007

In addition, Applicant has canceled claim 13. Its rejection is therefore mooted.

As for claim 46, Applicant has now corrected the clerical error, using strike through for deletions. Favorable action is respectfully requested.

III. Restriction Requirement

The Examiner notes that claims 47-54 are directed to an invention that is independent or distinct from the invention originally claimed for the following reasons: the claims are directed to a method for reducing tooth sensitivity, counteracting tooth decay or assisting in the regenerative process of periodontal tissues and a method for the prevention of tooth stain accumulation. Accordingly, claims 47-54 are withdrawn from consideration as being directed to a non-elected invention. See 37 CFR 1.142(b) and MPEP § 821.03.

Applicant has confirmed such restriction and the claims are now canceled from the present application. Applicant reserves the right to file the claims directed to a non-elected invention in a divisional.

IV. New Claims

New claims 55-63 are added. Claims 55 and 61 are independent. A corresponding number of claims are canceled.

Claim 55 is similar in scope to originally submitted claim 9. No new matter is added.

Claim 61 is fully supported throughout the specification, specifically, for example, by the disclosure, for example, on page 10, lines 5-10. No new matter is added.

SEP 25 2007

Applicant believes that these new claims are patentable over the references cited by the Examiner. There is no teaching in the cited art of the subject matter of claims 55 and 61. Favorable action is respectfully requested.

CONCLUSION

In view of the remarks provided above, it is believed that all pending claims are in condition for allowance. Applicants respectfully request favorable reconsideration and early allowance of all pending claims: 1-5, 7, 11-13, 16-35, 37-39, 41-43, 45-46, and new claims 55-63.

If a telephone conference would be helpful in resolving any issues concerning this communication, please contact the undersigned at 310-845-8501.

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Respectfully submitted,



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